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process for the recovery of tocopherols from a starting material containing fatty and sterol compounds. The Examiner contends that Hunt '252 discloses: (a) esterifying free fatty acids with a lower alcohol; (b) transesterifying the fatty acid glycerides with a lower alcohol in the presence of a zinc catalyst; (c) removing the excess lower alcohol, catalyst, and glycerol; and (d) reacting the resulting tocopherol/sterol mixture with a lower alcohol in the presence of an alkoxide catalyst to form free sterols and fatty acid alkyl esters. The Examiner further contends that Hunt '252 discloses transesterifying of the sterol esters at a temperature of from between 150°C and 240°C, for from 1 to 3 hours, under pressure. The Examiner notes that Hunt '669 discloses a similar process.

The Examiner contends that the instant claims only differ from the combined references by reciting the transesterification of the sterol esters at temperatures of from 115°C to 145°C at pressures of from 2 to 10 bar for periods of from 3 to 10 hours, whereas Hunt '252 discloses transesterification at temperatures of from 150°C to about 240°C under pressure for periods of from 10 minutes to 3 hours.

The Examiner argues that based upon the combined teachings of the Hunt references, the recovery of sterols from starting materials such as vegetable oils by a process comprising removal of the free fatty acids via esterification, transesterification of the fatty acid glycerides, removal of excess alcohol, catalyst and glycerol, followed by conversion of sterol esters into free sterols via transesterification would be obvious to one of ordinary skill in the art at the time the invention was made. Moreover, the Examiner argues that the differences in the temperature and reaction conditions for the transesterification of the sterol esters amounts to routine optimization which is within the skill level of one of ordinary skill in the art.

On this basis the Examiner argues that the claims are obvious in light of the combined Hunt references. Applicants strenuously, but respectfully, traverse the Examiner's rejection and the arguments and contentions in support thereof for the following reasons.

It is well-settled that in order for an Examiner to establish a *prima facie* case of obviousness, and thus shift the burden of proving non-obviousness onto Applicants, each of the following three criteria must be satisfied: (1) there must be some suggestion or motivation to modify or combine the references as suggested by the Examiner (it is not sufficient to say that

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the cited references can be combined or modified without a teaching in the prior art to suggest the desirability of the modification); (2) there must also be a reasonable expectation of success; and (3) the references as combined must collectively teach or suggest all limitations of the claims. The teaching or suggestion to combine and modify the cited art and the reasonable expectation of success must both be found in the prior art and not in Applicants' Specification. (M.P.E.P. §2143).

Applicants respectfully submit that the Hunt references fail to teach or suggest each and every element of Applicants claimed invention. Moreover, neither reference contains any teaching which would motivate one of ordinary skill in the art to modify the teachings of either Hunt reference as suggested by the Examiner in order to arrive at Applicants' claimed invention.

Applicants' claimed invention is directed to processes for producing sterols which comprise: (a) providing a fatty acid production-residue comprising sterol esters, free fatty acids, and partial glycerides; (b) removing the free fatty acids; (c) transesterifying the partial glycerides with a lower alcohol in the presence of a basic catalyst *under mild transesterification conditions* to form fatty acid alkyl esters and glycerol; (d) removing excess lower alcohol, the basic catalyst, the glycerol and the fatty acid alkyl esters, to form a bottom product comprising the sterol esters; and (e) transesterifying the sterol esters at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours to form free sterols.

Applicants have found that where the initial transesterification is conducted under mild conditions, such that very little free sterol is formed from the sterol esters, that the process can be conducted so as to obtain highly concentrated sterols, with less energy consumption. (See, Applicants' Specification, p. 2, line 29, through p. 3, line 9; & p. 6, lines 8-13).

Neither Hunt '252, nor Hunt '669, nor a combination of the two references, teaches a process for producing sterols wherein a first transesterification is performed under mild conditions such that very little sterol ester is converted to free sterol. Hunt '252 teaches the transesterification of the partial glycerides present in the starting material at temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1

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to about 3 hours", under pressure. (See, Hunt '252, col. 5, lines 20-24). These conditions are not mild.

The differences between these relatively harsh transesterification conditions disclosed in the Hunt references and the "mild" transesterification conditions employed in the first transesterification according to Applicants' claimed invention are evidenced in three ways. First, the conditions disclosed in Hunt '252, as set forth above, are different than the conditions which are set forth in Applicants' Specification as being mild. Applicants' preferred "mild" conditions for the first transesterification are temperatures of from 90°C to 145°C for from 2 to 20 minutes, under pressure. (See, Applicants' Specification, p. 6, lines 26-29). Second, upon reviewing Hunt '252, one can see that the second transesterification, the transesterification of the sterol esters, is conducted under the same conditions as the first transesterification, namely temperatures of "between about 150°C and about 240°C and in reaction times of 10 minutes or more, e.g. about 1 to about 3 hours", under pressure. (See, Hunt '252, col. 6, lines 24-28). Hunt '252 discloses two transesterifications performed under identical conditions. Based upon the fact that the first transesterification is conducted under the same conditions disclosed for the transesterification of the sterol esters, it is clear that some sterol ester can be transesterified during the first transesterification disclosed in Hunt '252. Accordingly, it is clear that the first transesterification disclosed in Hunt '252 is different than the mild transesterification of Applicants' claimed invention. Third, Hunt '669 specifically discloses that in the pre-esterification/transesterification portion of the process disclosed therein that, "the sterol fatty acid ester is reacted to sterol and fatty acid methyl ester." (See, Hunt '669, col. 6, lines 58-62).

The Examiner has argued that altering the transesterification parameters is routine optimization. Applicants respectfully disagree. Nothing in either Hunt reference indicates that lower temperatures or generally mild conditions should be used in the first transesterification, but not the second, nor is there any indication that shorter reaction times are optimum. As §§2144.05(II)(A&B) of the M.P.E.P. make clear, in order for an obviousness rejection to be based upon routine optimization of a parameter or variable, the allegedly optimizable variable must be recognized as a result-effective variable. Neither Hunt reference recognizes any advantage to be obtained by conducting the first transesterification under varying conditions,

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much less mild conditions such that a majority of the sterol ester present survives as the ester. Accordingly, there is no suggestion in either reference which would motivate one of ordinary skill in the art to utilize the mild conditions described by Applicants.

Finally, one of ordinary skill in the art would find no reasonable expectation of successfully increasing the yield and purity of sterols recovered via the process disclosed in the Hunt references by decreasing the reaction temperature and/or time during the first transesterification. Hunt '252 suggests carrying out the typical first transesterification for an amount of time and at temperatures such that about 90% of the fatty acids and fatty acid glycerides present are transesterified. (See, Hunt '252, col. 5, lines 24-29). This hardly suggests better results by shortening the reaction time.

Accordingly, as the Hunt references fail to teach or suggest each and every element of the claimed invention, fail to motivate modification of their teachings such that one of ordinary skill in the art would arrive at the claimed invention, and fail to provide one of ordinary skill in the art with a reasonable expectation of success, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the Hunt references. Withdrawal of the rejection of claims 1-3 and 6-32 under §103(a) is respectfully requested.

In Paper No. 8, the Examiner rejects claims 4 and 5 under 35 U.S.C. §103(a), as being unpatentable over Hunt '252 and Hunt '669, further in view of U.S. Pat. No. 6,448,423 of Hernandez, *et al.* (hereinafter referred to as "Hernandez"). Specifically, the Examiner contends that claims 4 and 5 further differ from the disclosure of the Hunt references by reciting the removal of free fatty acids by neutralization using sodium metasilicate, followed by precipitation and separation. However, the Examiner argues that Hernandez teaches the use of sodium metasilicate for the removal of free fatty acids from vegetable oils. The Examiner argues that it would have been obvious to one of ordinary skill in the art to have incorporated the teachings of Hernandez into the process of Hunt as an alternative, non-caustic means of removing free fatty acids.

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Based upon these arguments, the Examiner rejects claims 4 and 5 as being obvious. Applicants respectfully traverse this rejection and the arguments and contentions set forth in support thereof for the following reasons.

As described above, the combined Hunt references fails to establish a *prima facie* case of obviousness. The Hernandez reference fails to remedy the deficiencies of the Hunt references. None of the references teaches the dual transesterification wherein the first transesterification is conducted under mild conditions.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness based upon the combination of the Hunt references and the Hernandez reference. Withdrawal of the rejection of claims 4 and 5 under §103(a) is respectfully requested.

In view of the remarks set forth above, Applicants submit that all pending claims patentably distinguish over the prior art of record and known to Applicants, either alone or in combination. Accordingly, reconsideration, withdrawal of the rejections and a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

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(Date)

By: _____

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